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(54) VALVE ASSEMBLY

(71) We, BAXTER TRAVENOL LABORATORIES INC., a Corporation organised and existing under the laws of the State of Delaware, United States of America, of One Baxter Parkway, Deerfield, Illinois 60015, United States of America, do hereby declare the invention for which we pray that a Patent may be granted to us and the method by which it is to be performed to be particularly described in and by the following statement:—

In multiple blood bags and the like, it is desirable to provide an initial seal in the tubing between the multiple blood bags which can be opened without breaking the sterility within the system. This has been done in the past by various types of pointed cannulas position within the tubing itself and manipulated from the outside, to penetrate a diaphragm or membrane closing off the tubing. Also, a ball may be wedged into the tubing between the blood bags, to be removed by squeezing it out of the tubing to drop into the bag for opening of the valve.

Other breakaway structures within the tubing are known, so that, by manipulation from outside of the tubing, a rigid, closed-end tubular structure is broken in the middle to open a flow channel through the tubing. These structures, however, exhibit the disadvantage that they cannot be resealed once they have been opened. Also, they exhibit some difficulty of manipulation and use.

In accordance with one aspect of this invention there is provided a valve assembly including a flexible tube and valve means which comprises a tubular portion having a closed end, an elongate, relatively rigid member positioned within said flexible tube and carried on the exterior of said closed end, and frangible means to permit the opening of said closed end by rupture of an area of weakness defined in said closed end by manual manipulation of said elongate member from outside of the flexible tube.

The invention also provides a valve assembly including a flexible tube and valve means which comprises a tubular portion having a closed end, an elongate relatively rigid member positioned within said flexible tube and carried on the exterior of said closed end, and frangible means to permit the opening of said closed end by manual manipulation of said elongate member from outside of the flexible tube, said elongate rigid member being adapted to fit in sealing relation within said tubular portion after said opening to permit resealing of the tubular portion.

The elongate member may carry vanes along its length to provide fluid flow channels along it, so that the member does not obstruct flow within the tube.

Preferably, the vanes are of unequal length, with a pair of opposed vanes extending rearwardly of the end of the central portion of the rigid member. The portion of the flexible tube surrounding the rigid member preferably has a frusto-conical bore, positioned to receive and resiliently hold the opposed, longer vanes after the frangible means has been broken and the rigid member separated from the tubular portion. This can hold the rigid member in open position to prevent accidental reclosing of the tubular portion by the rigid member moving to obstruct the tubular portion.

Reference is made to the accompanying drawings, wherein:

Figure 1 is a plan view of a multiple blood bag apparatus incorporating a valve assembly according to the present invention;

Figure 2 is a greatly enlarged view of the valve assembly of Figure 1, with some of the parts shown in longitudinal section;

Figure 3 is a further enlarged view of a

portion of the assembly shown in Figure 2, taken partly in section, showing the closed end of a tubular portion and a portion of an elongate member in the original condition;

Figure 4 is a view similar to Figure 3, showing the same structure after the elongate member has been fractured from the closed end of the tubular portion and then inserted therein for resealing;

Figure 5 is a greatly enlarged view similar to Figure 3, but showing a modification of the structure;

Figure 6 is a sectional view taken along the line 6-6 of Figure 2;

Figure 7 is a greatly enlarged view of an alternative embodiment of a valve assembly according to the invention, which may also be used in the context of the system of Figure 1, with some of the parts shown in longitudinal section;

Figure 8 is a view similar to Figure 7 showing the valve assembly under the condition where the rigid member is being retained in its open position; and

Figure 9 is a perspective view, with portions broken away, of the tubular portion and rigid member of the embodiment of Figures 7 and 8.

Referring to Figures 1 to 4 and 6, there is shown a double blood-bag system comprising blood bags 10, 12 connected together by a length of tubing 16 in a known manner. The invention is also applicable to triple and quadruple bag systems, as desired, or any other system for use in the medical field or elsewhere valving inside of a flexible tube, controllable from the outside, is desired.

Blood bag 10 carries conventional donor tubing 22, only a fragment of which is shown, plus access ports 24 similar to those which are at the present time commercially available.

Valve means 26 is provided in the blood bag system, being sealingly retained in flow communication with blood bag 10, passing through the heat-sealed walls 28 of the blood bag as particularly shown in Figure 2.

The valve means 26 comprises a tubular portion 30, which is shown to be the portion retained by and passing through heat sealed portion 28 of the blood bag. Preferably, tubular portion 30 is formed to be of rigid plastics material, and is moulded integrally with elongate, generally rigid member 32, to form a single piece.

Tubular portion 30 defines a closed end 34. Elongate, rigid member 32 is carried on the exterior of the closed end as shown in Figure 2, and is positioned within the flexible tube 36 in sealed manner.

Flexible tube 36 may be sealed at one end 38 to tubular portion 30 by conventional solvent or heat sealing, and is crimped in the conventional manner at its other end 40 for sealing connection to tubing 16, which may be of narrower diameter. Accordingly, flexible tube 36, as part of tubing 16, which may also be flexible, provides an enlarged chamber in the flow line to receive the elongate, generally rigid member 32.

It will be noted that the enlarged chamber defined by flexible tube 36 may be fashioned to be somewhat longer than elongate member 32 to provide a space 42 for elongate member 32 to withdraw from its integral connection with tubular portion 30.

Elongate member 32 has a forwardly positioned, tapered portion 44 connected to closed end 34 of tubular portion 30.

Frangible means, specifically embodied in Figure 3 by an annular line of tearing weakness 46, extending completely around the front end of tapered portion 44 and defined in closed end 34, is provided. This line of tearing weakness is formed by a zone of decreased thickness at line of tearing weakness 46, defined between tapered portion 44 and tubular portion 30. Accordingly, when one wishes to open valve 26, one simply grasps the flexible tube 36 with the fingers and bends or twists rigid, elongate member 32 until a fracture takes place about annular line of weakness 46. Then, elongate member 32 can be moved rearwardly in the manner shown in Figure 2 by the phantom lines, to remove end 34 of the tubular portion 30 out of the way, and to open a flow channel through the tubular portion.

The tapered portion 44 of the elongate member 32 is proportioned so that, when one desires to reseal the tubular portion, one can press tapered portion 44 through the open end o tubular portion 30 to form a tight obstructing seal of fluid flow through the tubular portion 30, as shown in Figure 4. Accordingly, in this configuration, the structure that was initially closed end 34 of tubular portion 30, is pressed inwardly from the end of the tubular portion 30, as shown.

Thereafter, as desired, one can manually manipulate elongate member 32 into or out of sealing relationship with tubular portion 30, to open and close the latter as one may desire.

Elongate member 32 has a series of radially positioned, longitudinally extending vanes 48 arranged in cross-shaped cross-section, to provide longitudinal flow channels between the vanes for facilitating flow. Also, the diameter of outer tube 36 is proportioned to be larger than the largest transverse dimension of elongate member 32 so that, when broken off from tubular portion 30, fluid can easily flow around member 32 except when the member is put into position as shown in Figure 4 to block flow through tubular portion 30.

Referring to Figure 5, a slightly modified

embodiment of the apparatus described above is shown. In this embodiment, which is otherwise identical to the embodiment described above, annular groove 52 is provided in end wall 34*a* of tubular portion 30*a*. Accordingly, upon manipulation of elongate, generally rigid member 32*a* in a manner similar to that of the previous embodiment, tearing takes place in an annular region in the vicinity of groove 52 and weakened area 46*a* with somewhat greater ease than in the previous embodiment, because of groove 52. This embodiment can be used, when desired, with particularly tough plastics materials or in the instance that the dimensions of the device are large.

Also, stop members 54 may be provided, to prevent excessive penetration of rigid member 32*a* into tubular member 30*a*.

The described structures are easy to mould and perform reliably on a mass-produced basis.

Referring to Figures 7 to 9, another embodiment of the valve assembly of this invention is shown, and the valve means thereof may be utilized in place of the valve means 26 in the double blood bag system of Figure 1, or for any other desired use for controlling flow through tubing while being capable of manipulation from the outside of the tubing.

A blood bag 50 ,or any other container, defines a flat seal 52 which surrounds and holds flexible flow tubing 56 in sealing and communicating relation with the interior of bag 50. Tubing 56 is of relatively enlarged diameter, when compared with flow tubing 58, the two sections of tubing being conventionally joined together by a crimped or "four-way" heat seal 60 of the general type as shown in U.S. patent No. 2,702,036. Preferably, the junction between tubes 56 and 58 defines a bore 62 of frusto-conical shape as shown.

Secured within the proximal end of tubing 56 is a tubular portion 64, having a closed end 66, in a manner generally similar to the previous embodiment. Closed end 66 carries an elongate, generally rigid member 68 in integral relation thereto, for the purpose similar to that of the previous embodiment. In this specific instance, no specific line of weakness similar to lines 46 or 52 is included, but a tearing action can take place by bending of elongate member 68. The relatively thin area 70 between the inner wall of tubular portion 64 and the solid mass of elongate member 68 is accordingly stressed so that area 70, which is an annular area about member 68, is ruptured by manipulation of elongate member 68 from the exterior of tube 56, and thus constitutes a line of weakness without special provision, as by a groove.

Elongate, generally rigid member 68 includes a tapered portion 72, as in the previous embodiment, for fitting within the bore 74 of tubular portion 64 after opening for reclosing the structure again, as shown in phantom in Figure 8.

Studs 76 are provided to project outwardly to prevent the excess insertion of elongated member 68 into bore 74, which could render the removal of member 68 difficult at a later time. Studs 76 bear against the end of tubular portion 64 when member 68 is inserted to the proper depth, preventing further insertion.

As in the previous embodiments, elongate, generally rigid member 68 defines a plurality of longitudinal vanes 78, 80. However, vanes 80 are of unequal length to vane 78, being longer and preferably sufficiently long to exhibit a perceptible spring-like resilience.

Accordingly, upon manual opening of the valve by bending of generally rigid member 68 to rip open weak area 70, member 68 may be manually moved backwards, by axially collapsing, gripping and reextending flexible tube 56, to be placed into pinching, resilient, retention relation between vanes 80 and frusto-conical bore portion 62, as shown in Figure 8. Accordingly, rigid member 68 may be retained there, with the flow of blood or other fluid passing longitudinally around member 68 between the respective vanes 78, 80. This permits bidirectional flow of fluid as desired through the valve assembly without the danger of rigid member 68 drifting into obstructing relationship with bore 74 of tubular portion 64 until by positive manual action the rigid member 68 is released from its retained relation with bore 62.

Accordingly, as desired, the valve assembly may be positively opened and retained open, as shown in Figure 8, and may be positively resealed, after opening, by manipulation from outside the exterior of flexible tubing 56, after initial opening.

For the most convenient manipulation, flexible tubing 56 is fabricated to be quite soft so that it may be axially collapsed during manipulation of generally rigid member 68, with the tubing 56 convoluting outwardly as necessary during the process. Accordingly, the rigid member can be grasped and moved because of the flexibility of tubing 56.

Also, if desired, because of the flexibility of tube 56, an outside clamp may be used to retain rigid member 68 in any desired open or closed position.

As a further modification, reduced diameter tube 58 may be enlarged somewhat and the tapered portion 62 eliminated, so that vanes 80 can project directly into the reduced diameter tubing 58, flexing inwardly somewhat as they do, for an equivalent type of retention in the open position.

WHAT WE CLAIM IS:—

1. A valve assembly including a flexible tube and valve means which comprises: a tubular portion having a closed end, an elongate, relatively rigid member positioned within said flexible tube, and carried on the exterior of said closed end, and frangible means to permit the opening of said closed end by rupture of an area of weakness defined in said closed end by manual manipulation of said elongate member from outside of the flexible tube.

2. A valve assembly including a flexible tube and valve means which comprises: a tubular portion having a closed end; an elongate, relatively rigid member positioned within said flexible tube and carried on the exterior of said closed end, and frangible means to permit the opening of said closed end by manual manipulation of said elongate member from outside of the flexible tube, said elongate rigid member being adapted to fit in sealing relation within said tubular portion after said opening to permit resealing of the tubular portion.

3. A valve assembly according to Claim 2 in which the end of said rigid member which is adjacent said frangible means is tapered to facilitate said fitting in sealing relation within the tubular portion.

4. A valve assembly according to Claim 2 or 3 in which studs are provided on the rigid member to limit the extent of insertion of the rigid member into the tubular portion.

5. A valve assembly according to Claim 2, 3 or 4 in which said frangible means comprises a tearable annular line of weakness positioned at said closed end of the tubular portion.

6. A valve assembly according to Claim 5 in which said annular line of weakness includes an annular groove defined in said closed end on the side thereof opposite from the rigid member.

7. A valve assembly according to any preceding Claim in which said rigid member has longitudinal vanes to provide flow channels along its length.

8. A valve assembly according to Claim 7 in which the vanes of said rigid member are of unequal length, a pair of opposed vanes extending rearwardly of the end of the central portion of said rigid member, the flexible tube having a portion positioned to receive and resiliently hold said opposed vanes when the frangible means is broken and the rigid member is thereby separated from the tubular portion, so as to prevent accidental reclosing of the tubular portion by the rigid member moving to obstruct the tubular portion.

9. A valve assembly according to Claim 7 in which said portion of the flexible tube has a bore of frusto-conical shape.

10. A sterile, blood-compatible liquid container having a valve assembly according to any preceding claim secured thereto with the tubular portion in communication with the interior of the container.

11. A valve assembly according to any one of Claims 1 to 9 which is part of a multiple-blood-bag apparatus.

12. A valve assembly according to any one of Claims 1 to 9 in which said tubular portion is carried within a sealed edge of a blood bag with the closed end of said tubular portion spaced further from the bag than the opposite end of the tubular portion.

13. A valve assembly constructed substantially as herein described with reference to Figures 2, 3, 4 and 6, Figures 5 or Figures 7 to 9 of the accompanying drawings.

14. Blood-bag apparatus constructed substantially as herein described with reference to Figures 1, 2, 3, 4 and 6, Figures 1 and 5, or Figures 1, 7, 8 and 9 of the accompanying drawings.

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1573482 COMPLETE SPECIFICATION
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Sheet 1

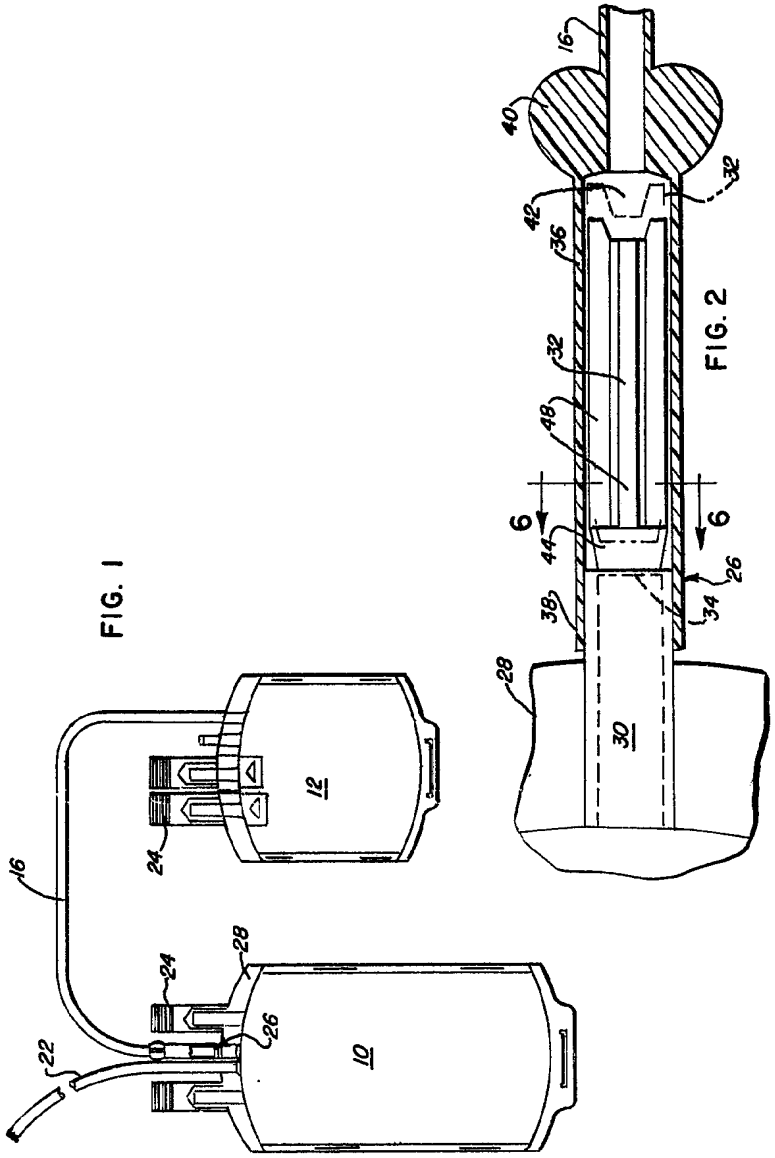

FIG. 1

FIG. 2

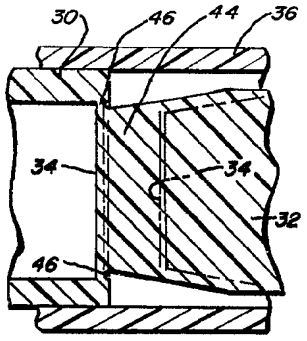

FIG. 3

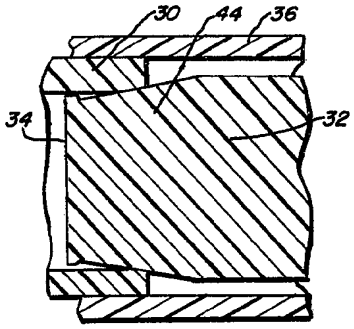

FIG. 4

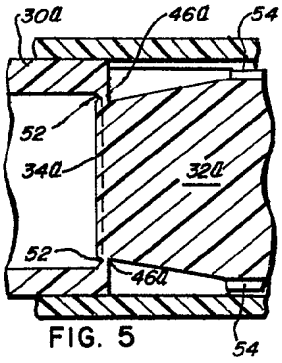

FIG. 5

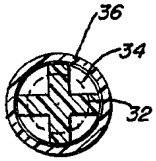

FIG. 6

1573482 COMPLETE SPECIFICATION
3 SHEETS *This drawing is a reproduction of the Original on a reduced scale*
Sheet 3

FIG. 7

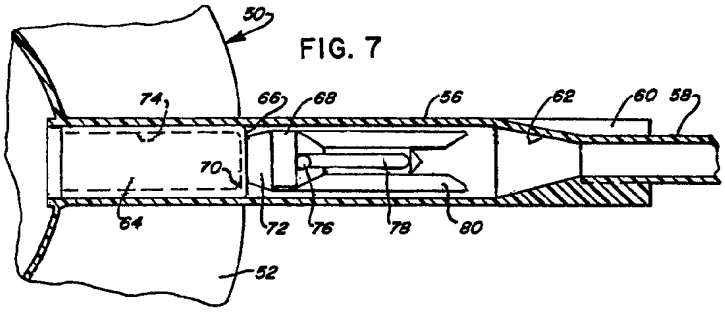

FIG. 8

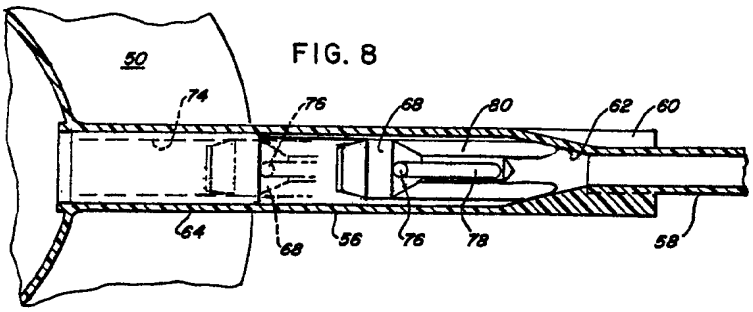

FIG. 9